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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,751	12/21/2000	Mark N. Hochman	3486-018	1104
22440	7590	06/05/2006	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC			HUH, BENJAMIN	
270 MADISON AVENUE			ART UNIT	
8TH FLOOR			PAPER NUMBER	
NEW YORK, NY 100160601			3767	

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,751	HOCHMAN, MARK N.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/18/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/06 has been entered.

Claim Rejections - 35 USC § 112

Claims 14-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's recitation of reducing pain-producing deflection is not enabled because applicant has not provided a disclosure to enable one skilled in the art to use the method to provide reduced pain needle deflection without undue experimentation. The claims are broadly recited with limitations to advancing a needle with simultaneous rotation to prevent pain from needle deflection. There is no description of the amount of deflection to avoid in order to reduce pain from any remaining deflection or the amount of deflection that can occur without a perception of pain. The level of predictability in the

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art is very low because the subject matter is subjective pain in biological systems.

Applicant has not provided any direction or working examples concerning the reduction of pain in advancing needles with reduced deflection. The quantity of experimentation would be large because of the biological variability and subjective nature of pain measurements. Because of these factors, the examiner concludes that the method of reducing pain producing deflections as recited in the claims is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15, 17, and 19, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U.S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a beveled needle of a syringe while inserting it through tissue in methods of injecting (1:15-23). This method will inherently eliminate pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14, 15, 17, 19, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN (U.S. Patent No. 3,244,172) in view of SPWELLO (US Patent No. 5,180,371). Brown discloses that it is well known in the art to turn or twist a beveled needle of a syringe while inserting it through tissue in methods of injecting (1:15-23). Brown shows a beveled needle in fig. 1. This method will inherently reduce or eliminate needle deflection and eliminate pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion. Brown does not disclose injecting drugs while the needle is advanced and rotated or using an advancing rate of 2-4 mm/sec. Spinello teaches advancing a needle through tissue, including an advancing rate of 2-4 mm/sec (Spinello's disclosure of a rate less than 6 mm/sec includes the claimed range), and delivering drug while advancing the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Spinello in the method disclosed as prior art in Brown in order to establish a range of volume over which the drug is administered and to reduce or eliminate pain as the needle is advanced (see col. 2, 11. 47-56).

Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN and SPINELLO as applied to claims 14 and 19 above, and further in view of KUHLE (US Patent No. 5,938,635). Brown and Spinello disclose that the insertion of

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a needle while rotating and delivering drug while advancing is known in the art. Brown and Spinello do not disclose rotating a needle up to 180 degrees in one direction during insertion to reduce deflection. Kuhle discloses a method of advancing a needle while rotating to reduce deflection of the needle. Kuhle teaches a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kuhle in the method of Brown and Spinello to recognize the desirability for accurately placing drug delivery needles and the established practice of rotating a needle during insertion.

Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN and SPINELLO and further in view of Garnier (US Patent No. 4381777). Brown and Spinello disclose the claimed invention except for rotating the needle in one direction, then the opposite direction as it is being advanced. Garnier teaches one directional and also bi-directional rotation (1:22-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Garnier in the method of Brown and Spinello in order to avoid injury or breakage. One of ordinary skill in the art would recognize the advantages of Garnier's rotation in soft tissue because Garnier discloses rotation through the injection process which includes both soft tissue (i.e., porous bone) as well as harder bone.

Claims 14, 15, 17, 19, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maroth (US Patent No. 3811442) in view of Spinello (US Patent No. 5180371). The Maroth reference discloses in figures 1-6 a hypodermic syringe with a beveled tip that is rotated and projected simultaneously in order to penetrate more effectively while reducing discomfort or pain to the subject, see col. 1 line 53 – col. 2 line 24, col. 3 line 35 – col. 4 line 27, and abstract. Therefore, this method would inherently reduce needle deflection and reduce pain during the syringe insertion because it makes the insertion easier with less tissue affected by the insertion. Now, even though Maroth does not explicitly disclose injecting drugs while the needle is advanced and rotated or using an advancing rate of 2-4 mm/sec attention is directed to Spinello. The Spinello reference teaches advancing a needle through tissue including a rate of 2-4 mm/sec and delivering a drug while advancing the needle, see col. 2 lines 47-56 & col. 5 lines 39 – col. 6 line 50. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Spinello in the method disclosed in Maroth in order to establish a range of volume over which the drug is administered and to reduce the pain as the needle is advanced.

Claims 18 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maroth (US Patent No. 3811442) in view of Spinello (US Patent No. 5180371) as applied in claims 14 & 19, and further in view of Kuhle (US Patent No. 5938635). While Maroth and Spinello disclose that the insertion of a needle while rotating and delivering drug while advancing is known in the art, the references do not explicitly disclose rotating a needle up to 180 degrees in one direction during insertion to reduce

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deflection. The Kuhle reference teaches a method of advancing a needle while rotating to reduce deflection of the needle and a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle, see col. 2 lines 28-64 and abstract. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Kuhle in the method of Maroth in view of Spinello to recognize the desirability for accurately placing drug delivery needles and the established practice of rotating a needle during insertion.

Claims 16, 20, & 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maroth (US Patent No. 3811442) in view of Spinello (US Patent No. 5180371) and further in view of Garnier (US Patent No. 4381777). Even though Maroth in view of Spinello does not explicitly disclose the rotating the needle in a first direction and then a second direction attention is directed to Garnier. The Garnier reference teaches one directional and bi-directional rotation of a needle, see col. 1 lines 22-34. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Garnier in the method of Maroth in view of Spinello in order to avoid injury or breakage of the needle. One of ordinary skill in the art would recognize the advantages of Garnier's rotation in soft tissue because Garnier discloses rotation through the injection process which includes both soft tissue as well as harder bone.

Response to Arguments

Applicant's arguments filed 4/18/06 have been fully considered but they are not persuasive.

Applicant's arguments with respect to the rejections under 35 USC 112 with respect to reducing pain producing deflection is not convincing and the rejection is maintained above.

Applicant has not provided any data to show that pain is reduced when a needle is advanced with rotation. Applicant's parameters mentioned on page 7 of remarks received 9/29/05 concern the reduction of needle bending. There is no data given that correlates needle bending to quantitative amounts of pain. Without this correlation, one of ordinary skill in the art would not know how much bending is permitted to achieve the claimed method of reducing pain. Additionally, since patients show different responses and tolerances to pain, lack of outward showing of pain does not mean the patient experienced a painless procedure, merely that the patient was able to tolerate the pain to a level below outward expression.

Applicant argues that the prior art does not disclose the needle to be advancing and rotating simultaneously, the examiner respectfully disagrees. The Brown reference discloses in col. 1 lines 20-22, that "... At times, a turning or twisting action may be employed to cause a needle to enter the tissues more easily ...". Wherein, the examiner interprets "enter" to mean advance in (i.e., move through) tissue, which means that the needle must be rotating and advancing simultaneously.

Applicant argues that the prior art does not disclose a method for reducing pain. Examiner respectfully disagrees wherein the Brown reference does disclose a method of reducing pain as it discloses a turning or twisting action that is employed while entering (seen as advancing into) a tissue "more easily" which is seen to reduce pain due to the ease of entrance of the needle.

Applicant's arguments with respect to the references Spinello, Kuhle, & Garnier concerning the simultaneous advancing and rotating of the needle as well as the method for reducing pain are addressed above in the response to arguments with respect to Brown.

Examiner suggests that the applicant disclose the location of usage for the needle and a specific diameter and length of the needle into the claims in order to possibly improve the status of the application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

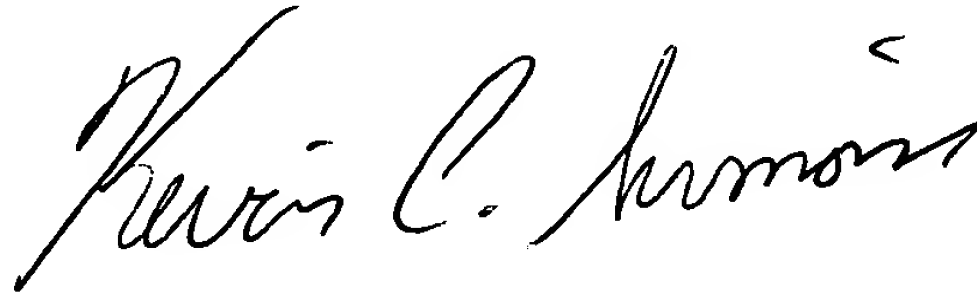
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN SIRMONS
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Kevin C. Sirmons". The signature is written in a cursive, flowing style with a large initial 'K'.